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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,258	12/08/2000	Friedel Frauendorfer	H01.2-9587	7047

490 7590 09/27/2002

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/27/2002 9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/719,258	Applicant(s) FRAUENDORFER, FRIEDEL	
	Examin r Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Extension of Time and Amendment B filed on June 28, 2002 are acknowledged.

Claims 1-11 are included in the prosecution of this application.

Rejection of claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin in combination with Acharya, as set forth above and further in view of Morozov et al (5728680), are maintained.

Response to Arguments

Applicant argues that Horrobin is silent on the problem of peroxidation of the PUFAs in capsules. Applicant argues that Acharya teaches xylose in hydrogel structures and the duration of release can be adapted by modification of the hydrogel structure. Lastly, applicant argues that Morozov only teaches improving shelf-life stability of pharmaceutical compositions by adding sugars such as xylose. The applicant further argues that Morozov is silent on PUFA and their peroxidation.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that the intended use of xylose in the oral dosage form does not hold patentable weight; therefore, Horrobin does not have to teach the peroxidation of PUFAs for the dosage form claims (1-5). Horrobin does teach the use of an enteric coating. Secondly, Archarya and Morozov are relied upon to provide the motivation of using xylose in the dosage form and its function. As recognized by the applicant, Archarya teaches manipulating the release rate by either adding hydrocolloids or complex carbohydrates such as xylose (col. 5/6, line 35 to line 20) to modify the release of a hydrogel structure. Archarya teaches disintegration of the polymeric matrix

(hydrogel structure) to release the active agent, just as a coating disintegrates to release an active. Morozov also teaches the use of xylose to increase shelf-stability of a pharmaceutical compositions; therefore it is obvious to one of ordinary skill in the art that xylose would slow down the peroxidation of the PUFAs. Therefore, one of ordinary skill in the art can ascertain from Archarya and Morozov that the function of xylose, whether used in the matrix or the coating, controls the release rate and provides shelf-life stability. The examiner points out that the claims rejected were the oral dosage claims and not the use claims.

New Rejections in view of Amendments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buser et al (WO 96/36329), cited prior art, in view of Cade et al (WO 97/04755), cited prior art .

Buser et al disclose a coated capsule (polyethylacrylate-methyl-methacrylate) containing mega-3 polyunsaturated acid (abstract and pg. 6). Buser teaches the preference of hard gelatin capsules. WO discloses these fatty acids are useful in treating inflammatory bowel disease and that enteric coatings overcome the belching and flatulence problems associated with the oral administration of these acids (pg. 3, lines 20-26).

Buser et al do not teach the gelatin capsule hardened by xylose.

Cade et al teach hard gelatin with reduced water transport or water vapor permeation by either laminating a polymer layer onto the gelatin shell or adding an additive to the gelatin formulation. Cade discloses that capsules with low permeability to water vapor reduce sensitivity to storage conditions and improves the protection of the compositions contained within (pg. 1, first paragraph). Further, permeation by the environment may cause the composition within to agglomerate or degrade chemically (pg. 2, fourth paragraph). Additives such as xylose, which are added to the gelatin solution, reduce water permeability and hygroscopicity (pg. 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings Buser et al and Cade et al. One would be motivated to harden a gelatin capsule with xylose since Cade et al teaches this reduces permeability by the environment that chemically degrades the contents of the capsules.

Further, Buser teaches a polymeric coating to reduce problems associated with the administration of fatty acids and Cade et al teaches the preservation of capsule fills may be done via polymeric coating or additives in the gelatin composition.

Claims 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Buser et al (WO 96/36329) in view of Cade et al (WO 97/04755) in further view of Horrobin (5422115).

As set forth above, Buser et al teaches the use of the instant fatty acids in treating IBD (Crohn's disease). Buser teaches using fish oil as the source for the polyunsaturated fatty acids.

Buser et al do not teach perilla oil as the source.

Horrobin teaches polyunsaturated fatty acids (omega 3-polyunsaturated fatty acids) in a gelatin capsule for the treatment of disorders such as Crohn's disease (col. 1, lines 36-43 and examples). Horrobin teaches several sources for obtaining polyunsaturated fatty acids (fish oil, perilla oil, linseed oil) (col. 6, lines55-66).

It would have been obvious to one of ordinary skill in the art at the time the invention was made use perilla oil as the source for the instant fatty acids since Horrobin teaches that the fatty acids may be obtained from fish oil or perilla oil to treat disorder such as Crohn's disease.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horrobin (5422115) in view of EP 0240581 or applicants statement.

Horrobin discloses a method of treating immunological/inflammatory disorders with oral compositions containing omega 3-polyunsaturated fatty acids in a gelatin

capsule (see examples). Horrobin teaches several sources for obtaining polyunsaturated fatty acids (fish oil, perilla oil, linseed oil) (col. 6, lines55-66). Horrobin teaches that polyunsaturated fatty acids for oral administration is not beneficial unless the active is administered in a manner which delays the release until after the stomach is passed (col. 3, lines 20-25). Horrobin teaches enteric coating (cellulose acetate phthalate) for the oral composition which would serve to delay of active substance release until the composition reaches the intestines (col5, line 5-12).

Although Horrobin discloses enteric coating, Horrobin does not teach the use of xylose for the enteric coating.

Applicant's specification on page 2 discloses that EP 0240581 teaches a gelatin capsule for pharmaceutical compositions for controlled release. EP teaches adding xylose to the gelatin capsule provides retarded release of the actives. EP teaches that slight or severe or complete resistance to gastric juices can be achieved depending on the amount of additive used (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Horrobin and EP. One would be motivated to do so since Horrobin teaches that lithium-fatty acid therapy is beneficial when the actives are released in the intestines and EP teaches that adding xylose in the gelatin capsule wall resists degradation of the capsule in gastric juices.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG

September 10, 2002

JOSE G. DEES
SUPERVISORY PATENT EXAMINER

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